Fact Sheet for Health Care Providers: Interpreting ReEBOV™ Antigen Rapid Test Results

February 24, 2015

Dear Health Care Provider:

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to authorize the use of the Corgenix Inc. ReEBOV™ Antigen Rapid Test to test for the presumptive presence of Ebola Zaire virus (detected in the West Africa outbreak in 2014) in fingerstick whole blood, plasma and serum specimens from individuals with signs and symptoms of Ebola virus infection in conjunction with epidemiological risk factors (including geographic locations with high prevalence of Ebola infection). The authorized ReEBOV™ Antigen Rapid Test is intended for circumstances when use of a rapid Ebola test is determined to be more appropriate than use of an authorized Ebola nucleic acid test, which has been demonstrated to be more sensitive in detecting the Ebola Zaire virus.

FDA issued this EUA based on data submitted by Corgenix Inc to FDA and on the U.S. Secretary of Health and Human Services' (HHS) declaration that circumstances exist to justify the emergency use of *in vitro* diagnostic tests for the detection of Ebola virus. This EUA will terminate when the HHS Secretary's declaration terminates, unless FDA revokes it sooner.

This test should be performed only on individuals with signs and symptoms of Ebola virus infection in conjunction with epidemiological risk factors (including geographic locations with high prevalence of Ebola infection). The authorized ReEBOV™ Antigen Rapid Test is not intended for use for general Ebola infection screening, such as airport screening or contact tracing. The ReEBOV™ Antigen Rapid Test is authorized for use in laboratories or facilities adequately equipped, trained, and capable of such testing (including treatment centers and public health clinics).

The information in this Fact Sheet is the minimum necessary to inform you of the significant known and potential risks and benefits of the emergency use of the ReEBOV™ Antigen Rapid Test. For more information on this EUA, please see FDA's website at http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm.

Why is this test needed at this time?

At this time, no FDA-approved/cleared tests that can detect Ebola Zaire virus (detected in the West Africa outbreak in 2014) in clinical specimens are available. Corgenix Inc. has developed the ReEBOV™ Antigen Rapid Test to detect Ebola Zaire virus (detected in the West Africa outbreak in 2014) infections in the specified population.

If infection with Ebola Zaire virus (detected in the West Africa outbreak in 2014) is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, the ReEBOV™ Antigen Rapid Test should be ordered only to presumptively diagnose Ebola Zaire virus (detected in the West Africa outbreak in 2014) infection. This test is authorized for use with fingerstick whole blood, plasma and serum. Specimens should be

collected with appropriate infection control precautions for Ebola viruses, according to instructions for the specimen collection device.

Use appropriate personal protective equipment when collecting and handling specimens from individuals suspected of having Ebola Zaire virus infection. The ReEBOV™ Antigen Rapid Test should be used only by trained personnel who have received specific training on the use of the ReEBOV™ Antigen Rapid Test.

Current information about Ebola virus disease for health care workers, including case definitions and infection control, is available in the guideline, *Infection Control for Viral Hemorrhagic Fevers in the African Health Care Setting*, developed by the U.S. Centers for Disease Control and Prevention (CDC) in conjunction with the World Health Organization (WHO) and found at http://www.cdc.gov/vhf/abroad/healthcare-workers.html. All information and guidelines, including those on Ebola Zaire virus laboratory testing, may change as we continue to learn more about this virus. Please check the CDC Ebola Hemorrhagic Fever website regularly for the most current information (**http://www.cdc.gov/vhf/ebola/index.html**).

What does it mean if the specimen tests positive for Ebola virus?

A positive test result from the ReEBOV™ Antigen Rapid Test indicates that the patient is presumptively infected with Ebola Zaire virus (detected in the West Africa outbreak in 2014). The test does not indicate the stage of infection. Laboratory test results should always be considered in the context of clinical observations and epidemiologic data in making a final diagnosis.

The ReEBOV™ Antigen Rapid Test has been designed to minimize the likelihood of false positive test results. However, in the event of a false positive result, the patient may be placed in isolation or in contact with other potentially infected/infected patients. While isolation or quarantine measures may likely already be in place for symptomatic persons meeting the case definition, there is a chance that quarantine may also be used for asymptomatic persons who test positive. All laboratories using this test must follow the recommended or standard confirmatory testing and reporting guidelines.

What does it mean if the specimen tests negative for Ebola Zaire virus?

A negative test presumes that Ebola virus (including Ebola Zaire virus detected in the West Africa outbreak in 2014) was not present at the detection level of the assay. However, negative results do not preclude Ebola virus infection, and should not be used as the sole basis for treatment, public health, or other patient management decisions. The clinical features of the illness and the type and risk of exposure are the keys to making patient management and isolation decisions. A negative ReEBOV™ Antigen Rapid Test result should not be interpreted as demonstrating that the patient does not have Ebola virus infection. The possibility of a false negative result should especially be considered if the patient's recent exposures or clinical presentation indicate that Ebola virus infection is likely, and diagnostic tests for other causes of illness are negative.

Reporting Adverse Events

Any adverse events should be sent to the following website/email address: orders@corgenix.com.

Give patients the *Fact Sheet for Patients: Understanding Results from the ReEBOV™ Antigen Rapid Test*.

Contact Information for Technical Assistance for the ReEBOV™ Antigen Rapid Test:

EMail: orders@corgenix.com

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Health care providers will be contacted by Corgenix Inc. in the event of any significant new findings observed during the course of the emergency use of the ReEBOV™ Antigen Rapid Test.